Sharekhan by BNP PARIBAS

Powered by the Sharekhan 3R Research Philosophy

Cipla Ltd

Pithampur plant issue to not impact existing products

Pharmaceuticals	Sharekhan code: CIPLA

Reco/View: Buy	↔	CMP: **Rs. 1,198**	Price Target: **Rs. 1,350**	↓

↑ Upgrade ↔ Maintain ↓ Downgrade

3R MATRIX

	+	=	-
Right Sector (RS)	✓		
Right Quality (RQ)	✓		
Right Valuation (RV)	✓		

+ Positive = Neutral – Negative

What has changed in 3R MATRIX

	Old		New
RS		↔	
RQ		↔	
RV		↔	

ESG Disclosure Score NEW

ESG RISK RATING Updated Apr 13, 2023	28.4

Medium Risk

NEGL	LOW	MED	HIGH	SEVERE
0-10	10-20	20-30	30-40	40+

Source: Morningstar

Company details

Market cap:	Rs. 96,786 cr
52-week high/low:	Rs. 1283/852
NSE volume: (No of shares)	18.9 lakh
BSE code:	500087
NSE code:	CIPLA
Free float: (No of shares)	53.7 cr

Shareholding (%)

Promoters	33.4
FII	3.8
DII	21.7
Others	41.1

Price chart

Price performance

(%)	1m	3m	6m	12m
Absolute	2.9	12.1	31.1	2.8
Relative to Sensex	4.2	14.5	20.5	-8.6

Sharekhan Research, Bloomberg

Summary

- Warning Letter for Pithampur unit on November 17, 2023, from the USFDA for the routine cGMP inspection conducted from 6-17 February 2023.
- USFDA has issued three critical observations, of which the key issue is of gAlbuterol where the company received 3000 complaints from the start of commercial manufacturing in April 2020 to December 2022
- We believe the Pithampur regulatory issue will not impact existing products but would likely delay new launches by 6-7 months. We lower our EPS estimates by 5% and 6% for FY2025E and FY2026E, respectively, to Rs. 52.8 and 62.3, as the plant contributes ~30% to US sales.
- After the price correction, stock trades at an attractive P/E of 22.7x/19.3x its FY2025E/FY2026E EPS. We have maintained Buy with a revised PT of Rs. 1,350.

Cipla received a warning letter for its Pithampur unit on November 17, 2023, after the plant received OAI status in August 2023. The warning letter was issued for cGMP inspection from 6-17 February 2023. The USFDA has issued three critical observations out of which the USFDA emphasised on its key drug gAlbuterol which has received 3,000 complaints from the start of commercial activity in April 2020-December 2022. From the 3,000 complaints received, approximately 91% complaints were categorized as 'no spray' or 'empty/less weight.' Furthermore, many of these complaints remained open for extended periods of time i.e., up to 314 days. The USFDA also notified about inadequate response for valve manufacture and concluded that the queries on 'defective valves' remained unresolved. gAlbuterol is one of the key products of Cipla with ~13% market share. Cipla's US sales have grown for 14 quarters in a row to US$229 mn in Q2FY2024.

Issues at Pithampur unit escalates with a Warning Letter, import alert probability low: Cipla received a Warning Letter for its Pithampur unit on November 17, 2023 from the USFDA for the routine cGMP inspection conducted from 6-17 February 2023. The warning letter was issued after the plant received OAI status along with eight observations in August 2023. The USFDA issued three critical observations, of which the key issue is of gAlbuterol, where the company received 3,000 complaints from the start of commercial manufacturing in April 2020 to December 2022. In January 2021, the company concluded that there was no risk to product quality and patient safety based on a risk assessment. On the contrary, approximately 91% of these complaints were categorised as 'no spray' or 'empty/less weight.' Furthermore, many of these complaints remained open for extended periods of time (up to 314 days). The second observation was that the company failed to establish and follow appropriate written procedures designed to prevent microbiological contamination of purportedly sterile drug products, including validation of all aseptic and sterilisation processes. The third observation was that the company failed to establish adequate written responsibilities and procedures applicable to the quality-control unit and to follow such written procedures. Amid all these observations, management clarifies that these observations do not have any meaningful impact on the company's existing products.

gAdvair launch may get delayed to FY2025E, little impact on existing products: Cipla received USFDA observation for its key product, gAlbuterol, which commands ~13% market share. Cipla's USD sales are at USD733mn, of which we believe gAlbuterol's sales are likely to be at USD16-20mn for FY2023. The impact of USFDA observation on Cipla's earnings are likely to be minimal as Cipla has strengthened its US portfolio, where its key product, Lanreotide, has improved its market share to 20%. As a result of the Warning Letter, the company's new product launches, such as gAdvair, which are expected to have significant sales, will be hampered. gAdvair's sales are expected to delay by further six months from its estimated time to file in H2FY2024E. gAdvair has a significant potential as the market size is worth USD700mn. There are a few players who specialise in the respiratory portfolio and Cipla, despite the delay in the launch, is expected to enjoy FTF for gAdvair.

Exit of current promoters with a better deal value would be a positive catalyst: Cipla is undergoing a succession planning issue and have been actively looking for suitable buyers to buy the controlling stake in the company. As per media news, many pharma companies along with PE players have been at the forefront of buying the controlling stake with Torrent Pharma being at the forefront. Any fructification of the deal with good valuation would allay street fear of succession and act as a positive catalyst for the stock's performance.

Our Call

View – Maintain Buy with a revised PT of Rs. 1,350: With Goa plant already under WL and Pithampur unit receiving additional Warning Letter, we believe timeline of the new launches will get impacted; however, there would be no impact existing products. The resolution timeline is tricky and remains a key monitorable for the stock. We have reduced our EPS by 5% and 6% for FY2025E and FY2026E, respectively, to Rs. 52.9 and Rs. 61.2, respectively, as the plant contributes ~30% to US sales. The stock is trading at an attractive P/E valuation of 22.7x/19.3x its FY2025E/FY2026E EPS and proportionately we have marginally lowered our price target (PT) to Rs. 1,350 and maintain our Buy rating.

Key Risks

USFDA issues resolution timeline and potential import alert are key risks.

Valuation (Consolidated) Rs cr

Particulars	FY22	FY23	FY24E	FY25E	FY26E
Sales	21763.3	22753.1	25400.8	27821.7	31021.2
EBITDA	4,553	5,027	6,037	6,706	7,560
EBITDA M (%)	20.9	22.1	23.8	24.1	24.4
PAT	2516.8	2801.9	3824.2	4263.0	4932.9
NPM (%)	11.6	12.3	15.1	15.3	15.9
EPS	33.5	37.0	47.4	52.9	61.2
P/E	35.8	32.4	25.3	22.7	19.6
P/BV	4.6	4.1	3.6	3.2	2.8
EV/EBIDTA	21.1	19.1	15.9	14.3	12.7
ROE (%)	12.8	12.6	14.2	13.9	14.1
ROCE (%)	16.0	15.7	18.0	17.9	18.3

Source: Company; Sharekhan estimates

Outlook and Valuation

■ Sector view - Input cost easing with companies focusing on complex product launches

Over the years, Indian pharmaceutical companies have established themselves as a dependable source for global pharma companies. The confluence of other factors, including a focus on specialty/complex products in addition to emerging opportunities in the API space, would be key growth drivers over the long term. The sector is witnessing the easing of input cost like raw-material cost, freight cost, and power cost, which aid the sector in expanding margins. The sector is also witnessing the easing of price erosion followed by increasing contributions from new product launches. We believe the sector is in a sweet spot, where it is experiencing a healthy product mix and cost rationalisation, which increases operational profit of the companies. The sector is mainly a low-debt sector and increasing operational profit followed by experiencing the advantage of low tax rate due to its operations in the SEZ sector; hence, overall, we have a positive view of the sector.

■ Company outlook - Long-term outlook is strong

Cipla has seen an increase in the US revenue base to USD222 million a quarter vs. an average base of USD160 million before, driven by differentiated products. The company's differentiated products comprising respiratory and peptide products are performing well in the US. Although some of the concerns are that gAbraxane's and gAdvair's launches are likely to be delayed due to USFDA compliance pending at Indore and Goa plants, but they are being de-risked. At the same time, India's market growth is recovering and is expected to continue to grow on account of a strong set of product launches in branded prescription and trade generics. The rebalanced supply chain in the US coupled with a strong set of existing products such as gRevlimid and Lanreotide should continue to drive profitable growth over FY2023-FY2025E.

■ Valuation - Maintain Buy with a revised PT of Rs. 1,350

With Goa plant already under WL and Pithampur unit receiving additional Warning Letter, we believe timeline of the new launches will get impacted; however, there would be no impact existing products. The resolution timeline is tricky and remains a key monitorable for the stock. We have reduced our EPS by 5% and 6% for FY2025E and FY2026E, respectively, to Rs. 52.9 and Rs. 61.2, respectively, as the plant contributes ~30% to US sales. The stock is trading at an attractive P/E valuation of 22.7x/19.3x its FY2025E/FY2026E EPS. We have marginally lowered our PT to Rs. 1,350 and maintain our Buy rating.

About company

Cipla is a global pharmaceutical company with a geographically diversified presence and products registered in more than 170 countries. Indian branded formulations account for more than 40% of business and Cipla is among the top three players in the market. In the past, the company believed in the partnership model for international markets. However, in the past three years, the company has been undergoing a strategic shift and has started setting up its own front-end divisions. Cipla is also a well-known global player in inhalers and antiretrovirals. Going forward, the company is planning to launch combination inhalers in larger markets such as the US and EU and is setting up its own front ends to drive growth.

Investment theme

Cipla banks on its branded business in India and South Africa, both of which together contribute ~56% to the business. A solid presence in the chronic segment in domestic markets along with a market leadership position in select chronic therapies such as respiratory, inhalation, and urology bodes well for the company. The recently launched complex and differentiated products have done extremely well in the US. Additionally, the India market would recover its sales growth post the high base effect from COVID-19 wanes away. At the same time, SAGA is recovering with market-beating growth. Although its key launches stand pending due to USFDA facility clearances, they are being de-risked with launches likely over the next two years.

Key Risks

- Currency fluctuations could have an adverse impact.
- Delay in key product approvals/faster approvals for competitors.
- Any regulatory changes in India or South Africa or the US could affect business.

Additional Data

Key management personnel

Dr. Y. K. Hamied	Chairman
Samina Hamied	Executive Vice-Chairperson
Ashish Adukia	Chief Financial Officer
Rajendra Chopra	Company Secretary

Source: Company

Top 10 shareholders

Sr. No.	Holder Name	Holding (%)
1	SBI Funds Management	4.65
2	Blackrock Inc.	3.45
3	Government Pension	2.48
4	Vanguard Group Inc.	2.43
5	Norges Bank	2.30
6	Life Insurance Corp	2.29
7	Government Pension Fund	2.25
8	HDFC AMC	1.83
9	NPS Trust AC	1.60
10	GQG Partners	1.16

Source: Bloomberg

Understanding the Sharekhan 3R Matrix

Right Sector	
Positive	Strong industry fundamentals (favorable demand-supply scenario, consistent industry growth), increasing investments, higher entry barrier, and favorable government policies
Neutral	Stagnancy in the industry growth due to macro factors and lower incremental investments by Government/private companies
Negative	Unable to recover from low in the stable economic environment, adverse government policies affecting the business fundamentals and global challenges (currency headwinds and unfavorable policies implemented by global industrial institutions) and any significant increase in commodity prices affecting profitability.
Right Quality	
Positive	Sector leader, Strong management bandwidth, Strong financial track-record, Healthy Balance sheet/cash flows, differentiated product/service portfolio and Good corporate governance.
Neutral	Macro slowdown affecting near term growth profile, Untoward events such as natural calamities resulting in near term uncertainty, Company specific events such as factory shutdown, lack of positive triggers/events in near term, raw material price movement turning unfavourable
Negative	Weakening growth trend led by led by external/internal factors, reshuffling of key management personal, questionable corporate governance, high commodity prices/ weak realisation environment resulting in margin pressure and detoriating balance sheet
Right Valuation	
Positive	Strong earnings growth expectation and improving return ratios but valuations are trading at discount to industry leaders/historical average multiples, Expansion in valuation multiple due to expected outperformance amongst its peers and Industry up-cycle with conducive business environment.
Neutral	Trading at par to historical valuations and having limited scope of expansion in valuation multiples.
Negative	Trading at premium valuations but earnings outlook are weak; Emergence of roadblocks such as corporate governance issue, adverse government policies and bleak global macro environment etc warranting for lower than historical valuation multiple.

Source: Sharekhan Research

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