Sharekhan by BNP PARIBAS

Powered by the Sharekhan 3R Research Philosophy

Stock Update

Company Update

Lupin Ltd

gSpiriva a boost, yet stay on guard

Pharmaceuticals	Sharekhan code: LUPIN

Reco/View: Reduce	↔	CMP: **Rs. 858**	Price Target: **Rs. 779**	↑

↑ 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	35.2
Updated Apr 13, 2023	

High Risk

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

Source: Morningstar

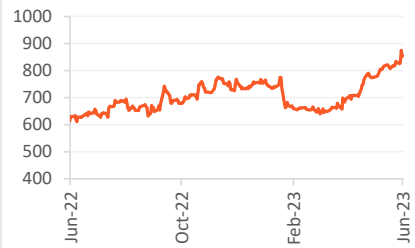
Company details

Market cap:	Rs. 39,055 cr
52-week high/low:	Rs. 885 / 603
NSE volume: (No of shares)	21.7 lakh
BSE code:	500257
NSE code:	LUPIN
Free float: (No of shares)	21.4 cr

Shareholding (%)

Promoters	52.9
FII	13.3
DII	29.2
Others	4.55

Price chart



Price performance

(%)	1m	3m	6m	12m
Absolute	10.5	32.3	15.5	36.5
Relative to Sensex	8.9	23.6	10.2	16.0

Sharekhan Research, Bloomberg

Summary

- Though the launch of a new drug boosts revenue and earnings prospects for Lupin over the next two fiscals, however uncertain margins trajectory and weak return ratios coupled with recent runup in stock baked in the positives, rich valuation at ~35.7x /~23.1x its FY24/FY25E EPS make us cautious on stock, thus we maintain a REDUCE rating, while we raise our PT to Rs 779.
- After a long wait, the USFDA granted final approval for gSpiriva, a generic equivalent for the Spiriva Handihaler, worth $1.26 billion in US annual sales. Lupin's exclusive rights for the drug would help it clock double-digit revenue growth in the segment over the next two years.
- The drug's high value and limited competition status will add ~$96 million in FY24E and ~$76 million in FY25E to Lupin's US revenues, respectively, which makes us raise our revenue and earnings growth estimates by ~4.3%/ ~7.2% and ~7.4%/~5.4%, for FY24E and FY25E, respectively.
- Lupin eyes a rise in EBITDA margins with the addition of gSpiriva. Though it has guided for exit EBITDA margin of 18% in FY2024E, margins are likely to lag those of its peers. A comeback in margins will ride hugely on cost rationalisation at key plants and other cost-saving initiatives and an overall improvement in US business margins, which seems unlikely.

After a long wait, the USFDA granted Lupin the final approval for the ANDA on the Tiotropium Bromide Inhalation Powder (18 mcg/capsule). The drug is a generic equivalent of the Spiriva HandiHaler of Boehringer Ingelheim Pharmaceuticals, Inc. The generic will be manufactured at Lupin's Pithampur facility in India. Spiriva HandiHaler had estimated annual sales of $1.26 billion in the US (IQVIA MAT - March 2023). gSpiriva will be the first generic version of the product and a launch is likely in H1FY24 in the US. Given a likely no/limited competition status for gSpiriva in 2-3 years, we believe the company can generate incremental revenue of ~$170.6 million from gSpiriva in the next two years. We thus raise revenue/PAT estimates for Lupin by ~4.3%/~7.4% for FY24E and by ~7.2%/~5.4% for FY25E, respectively. Adjusted earnings are likely to clock a ~119% CAGR versus a ~113% CAGR over FY23-FY25E rise expected earlier. Lupin eyes a rise in EBITDA margins with the addition of gSpiriva. Though it has guided for exit EBITDA margin of 18% in FY2024E, margins are likely to lag those of its peers. A comeback in margins will ride hugely on cost rationalisation at key plants and other cost-saving initiatives and an overall improvement in US business margins, which seems unlikely. Also, the stock appears overvalued vis-à-vis peers (at ~35.7x /~23.1x its FY24/FY25E EPS vs. ~20.0x/~17.0x for peers) and thus we maintain a REDUCE rating, while we raise our PT to Rs 779.

- **gSpiriva nod to boost US growth:** The USFDA's nod comes in line with Lupin's expectation of the same in H1FY24. gSpiriva' s addition is likely to fetch $170.6 million in revenues over the next 2 years, which would boost US revenue growth to double-digits – Around 19% and 15% p.a. (versus 5% estimated earlier) in FY24E and FY25E, respectively.
- **gSpiriva besides other exclusive generic products to drive double-digit growth and profitability in the US:** Product approvals for gSpiriva and gDarunavir where Lupin has a 180-day exclusivity or (first-to-file) FTF status would drive strong growth in the US. gSpiriva is likely to be launched in H1FY24 with estimated pre-launch annual sales of $1.26 billion. Post gSpiriva's launch Lupin's US revenues are likely to rise to a quarterly run-rate of $200 million in FY24E and $225 million in FY25E from $175 million in Q4FY23.
- **Reduced in-licensed products in India business to aid growth:** Lupin believes that it is outpacing the Indian market's growth (excluding share of in-licensed products). The company expects share of in-licensed products in the Indian market will come down over a period, after a few see patents expire in FY24 and FY25. Additionally, an increase in prices announced by the government for NLEM products will be favorably affecting India sales to the tune of Rs. 100 crores for FY24E.
- **Margin trajectory looks uncertain, return ratios remain weak:** With gSpiriva added to its kitty, Lupin expects its EBITDA margins to recover. Even though, as Lupin has guided for exit EBITDA margin of 18% in FY2024E. However, margins are likely to lag those of peers. Cost rationalisation in Somerset (NJ), Ankleshwar will be critical in ensuring a comeback in margins along with other cost-saving initiatives and an overall improvement in US business margins, which seems unlikely. Further, despite an improvement in profitability, return ratio profile remains weaker than peers.

Our Call

Positives baked in rich valuation, maintain Reduce: Lupin's FTF exclusivity for gSpiriva is likely to add substantially to Lupin's US revenue, making it clock in double-digit growth for the segment over the next 2 years. We believe the high value and limited competition status of gSpiriva will add ~$96 million in FY24E and ~$76 million in FY25E in Lupin's US revenues, respectively. As a result, we raise revenue and earnings growth estimates by ~4.3%/ ~7.4% and ~7.2%/~5.4%, for FY24E and FY25E. Though the launch of a new drug boosts revenue and earnings prospects for Lupin over the next two fiscals, however uncertain margins trajectory and weak return ratios coupled with recent runup in stock baked in the positives, rich valuation at ~35.7x /~23.1x its FY24/FY25E EPS make us cautious on stock, thus we maintain a REDUCE rating, while we raise our PT to Rs 779.

Key Risks

1) Adverse regulatory developments including outcome of inspections can impact earnings prospects; 2) Currency fluctuation risks.

Valuation (Consolidated) Rs cr

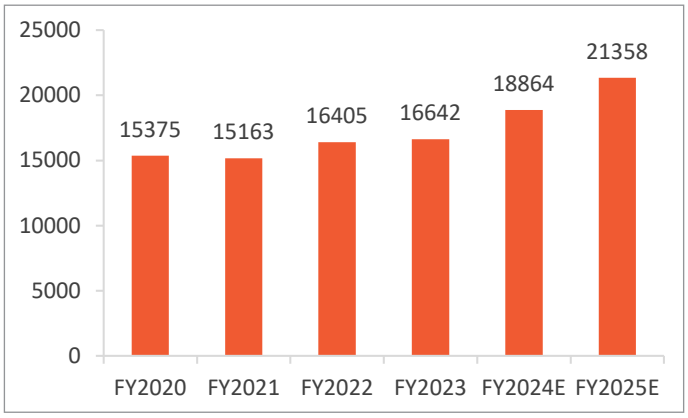
Particulars	FY2021	FY2022	FY2023	FY2024E	FY2025E
Net sales	15,163.0	16,405.5	16,641.7	18,864	21,358
EBITDA Margin (%)	16.9	12.8	10.3	15.0	18.2
Adj. PAT	1,216.5	1,122.2	352.5	1,092.5	1,685.9
Adj. EPS (Rs)	26.8	24.7	7.8	24.0	37.1
PER (x)	32.0	34.8	110.7	35.7	23.1
EV/EBITDA (x)	16.8	20.1	24.6	11.7	8.0
ROCE (%)	9.0	8.4	5.1	10.6	15.0
RONW (%)	8.8	9.2	2.8	8.3	11.6

Source: Company; Sharekhan estimates

- **Approval for gSpiriva to drive double-digit revenue growth in the US:** The company has received approval for gSpiriva in Q1FY24 from the USFDA, in line with its confidence of gaining its approval in H1FY24. It has been a blockbuster drug belonging to Boehringer Ingelheim Pharmaceuticals, Inc. with an annual market size of $1.26 billion in the US. It is the first generic approval of the blockbuster and limited competition drug gSpiriva. Hence, we believe that the company is likely to gain ~$170.6 million of revenue over the next two years from it. This makes Lupin to likely to grow its US revenue at a double-digit rate of ~19% and ~15% per annum (vs. 5% estimated earlier) in FY24E and FY25E, respectively.
- **gSpiriva besides other exclusive generic products to drive double digit growth and profitability in the US:** The product approval for gSpiriva and gDarunavir where Lupin has a 180-day exclusivity or FTF status are expected to drive strong growth in the US segment. Darunavir has been launched in the US in Q1FY24, which has an annual estimated sales of USD 308 million. gSpiriva is likely to be launched in H1FY24. Also, the company expects ~4-5 injectable products to be launched in FY24. The company has 55 First to File (FTFs) and 22 Exclusive FTFs with substantial ongoing investments in complex products such as inhalation, injectables and biosimilars. Additionally, the company has 155 ANDAs pending approval including over 30 injectables. These limited-competition generic launches and specialty products are expected to boost revenue and profitability considerably in the short to medium term. We expect the US revenue to rise to a quarterly run rate of $200 million in FY24E and $225 million in FY25E from $175 million quarterly run rate seen in Q4FY23.
- **Reduced share of in-licensed products in India business to aid in profitable growth:** The company believes that it has been growing better than the market growth in India excluding share of in-licensed products. The company expects that the share of in-licensed products for India market will come down over a period, after a few in-licensed products will see patent expiry in FY24 and FY25. A large part of the in-licensed products is for diabetes segment. India market growth has been coming from overall portfolio performing in line or above the industry growth. Softness is seen in the diabetes and cardiac markets though. A rise in prices announced by the government for NLEM products will bode well for India sales to the tune of Rs. 100 crore FY24E.

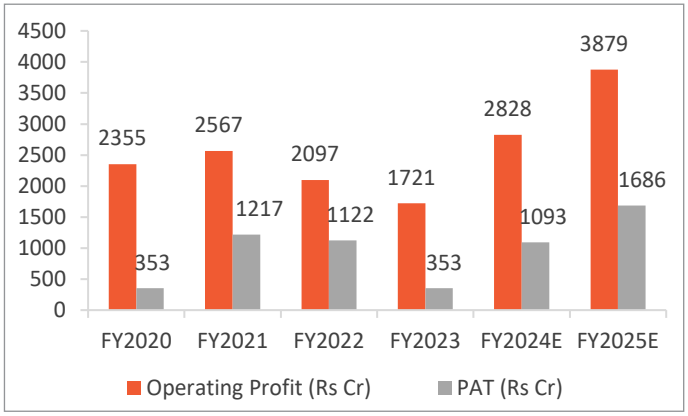
Financials in charts

Sales Trends (Rs Cr)



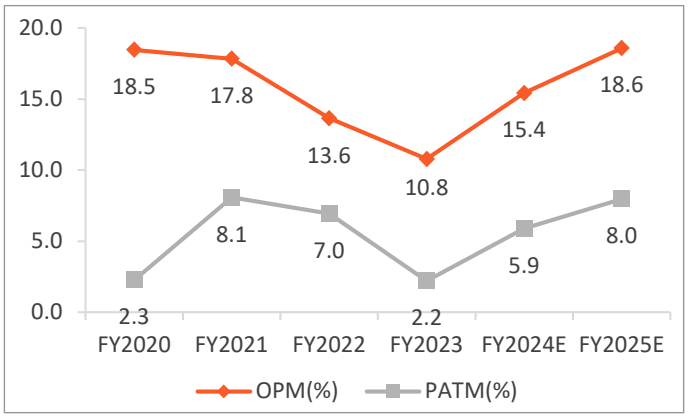
Source: Company, Sharekhan Research

Operating Profit - PAT Trends



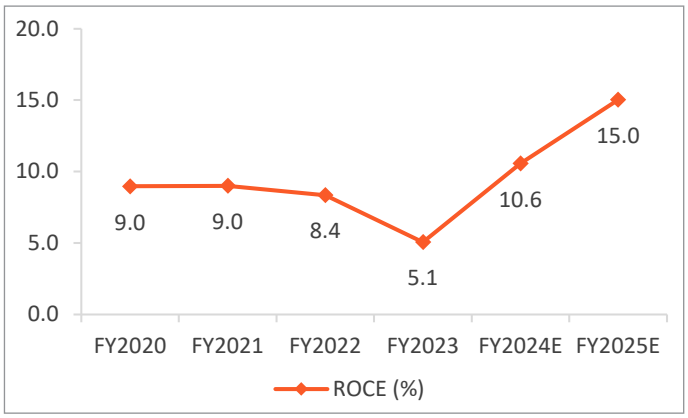
Source: Company, Sharekhan Research

Margins to improve



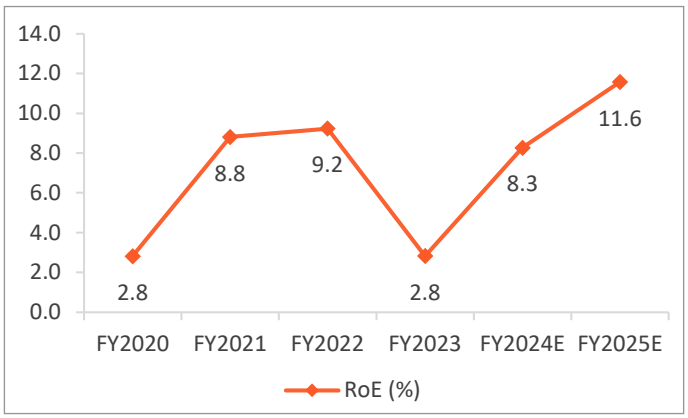
Source: Company, Sharekhan Research

ROCE Trends (%)



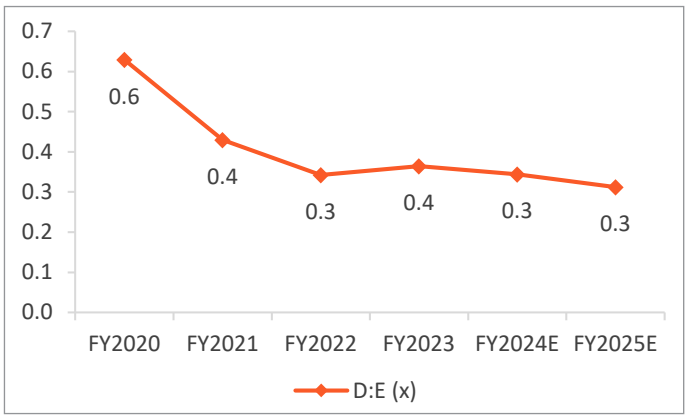
Source: Company, Sharekhan Research

RoE Trends (%)



Source: Company, Sharekhan Research

Debt : Equity (x)



Source: Company, Sharekhan Research

Outlook and Valuation

■ Sector view - Regulatory concerns and pricing erosion prove a hurdle over the short-medium term

Over the years, Indian pharmaceutical companies have established themselves as a dependable source for global pharmaceutical companies. A mix 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. However, ongoing USFDA plant inspections and a few companies being issued Form-483s with observations point at apparent regulatory concerns. We believe that in the near term, based on headwinds that may drag the performance, especially in the API and CDMO space and for large pharma players seeing USFDA OAI or WL status on their facilities, we have a Neutral view of the sector.

■ Company outlook - Looking bleak

Lupin has been trying to restructure or optimise the US business and enhance it with the help of launching of complex generics and specialty products in respiratory, injectables and biosimilars. Additionally, it has embarked on adding ~1,000 sales representatives in India; also, the loss of Cidmus brand from Cardio therapy and generalization of gliptins, a part of anti-diabetic portfolio in India has led to slower growth for the India business. Also, some of its facilities like Mandideep unit I facility in Madhya Pradesh has been issued with form-483 while its Tarapur facility has been issued a warning letter against it since Q2FY23. Even the Pune facility has been issued with form 483 by the USFDA. For Lupin, all these point to likely headwinds to profitable growth in near to medium term.

■ Valuation

Lupin's FTF exclusivity for gSpiriva is likely to add substantially to Lupin's US revenue, making it clock in double-digit growth for the segment over the next 2 years. We believe the high value and limited competition of gSpiriva will add ~$96 million in FY24E and ~$76 million in FY25E in Lupin's US revenues, respectively. As a result, we raise revenue and earnings growth estimates by ~4.3%/ ~7.4% and ~7.2%/~5.4%, for FY24E and FY25E, respectively and increase the PT to Rs. 779. However, as the stock still appears overvalued while trading at ~35.7x /~23.1x its FY24/FY25E EPS estimates vs. peers trading at ~20.0x/~17.0x their FY24E/FY25E EPS estimates, respectively, we maintain the rating to REDUCE.

Peer Comparison

Companies	CMP (Rs/ Share)	MCAP (Rs Cr)	P/E (x)			EV / EBITDA (x)			RoE (%)		
			FY23	FY24E	FY25E	FY23	FY24E	FY25E	FY23	FY24E	FY25E
Lupin	857	39,055	110.7	35.7	23.1	24.6	11.7	8.0	2.8	8.3	11.6
Cipla	990.3	79,868	22.9	20.9	17.5	13.7	11.6	9.6	13.8	15.1	15.5
Sun Pharma	990.2	2,37,882	27.1	24.7	22.4	20.6	18.3	16.0	14.8	14.1	14.0
Torrent Pharma	1,863.3	63,054	50.9	34.5	29.7	24.0	17.5	15.1	20.3	26.9	26.0
Zydus Lifesciences	557.0	56,389	22.8	18.9	17.0	14.8	11.9	11.6	14.1	13.9	13.7

Source: Company; Sharekhan Research

About company

Over the past decade, Lupin has established itself as a leading generic player from India. US and India are the company's largest markets and contribute around 37% and 35%, respectively, to the FY2021 sales of the company. The company develops and commercialises a wide range of branded and generic formulations, biotechnology products, and APIs in over 100 markets in the US, India, South Africa, across Asia Pacific (APAC), Latin America (LATAM), Europe, and Middle East regions. While in India, Lupin is among the top 10 and fastest-growing companies as well. The company is also among the top five companies in terms of prescriptions in the US. Therapy wise, the company has a leadership position in the cardiovascular, anti-diabetic, and respiratory segments and has a significant presence in the anti-infective, gastrointestinal (GI), central nervous system (CNS), and women's health segments. In terms of manufacturing capabilities, Lupin has 15 manufacturing sites and seven research centres globally.

Investment theme

Lupin is one of the leading pharmaceutical companies and is present in most markets globally. After establishing itself as a major player in the generics space, the company is making efforts to improve its presence in the specialty business. The US is a key market for Lupin where it is grappling with the issues surrounding high intensity of competition in Oral Solid Dosage (OSD) segment in the US. It has been trying to restructure or optimize the US business and enhance it with the help of launching of complex generics and specialty products in respiratory, injectables and biosimilar segments. However, lower than consolidated EBITDA margins in the US, is restricting its ability to enhance its overall margins to historical levels. This, besides the delay in the key product launches such as that of Spiriva (whose priority review is pending with the USFDA which is likely by April 23 or July 23) is a key hurdle as well. Additionally, it has embarked on adding sales representatives in India by another 1,000; also, the loss of Cidmus brand from Cardio therapy and generalization of gliptins, a part of anti-diabetic portfolio in India has led to slower growth for the India business. Also, some of its facilities like Mandideep unit I facility in Madhya Pradesh has been issued with form 483 while its Tarapur facility has warning letter issued against it since Q2FY23. Even Pune facility has been issued with the form 483 by the USFDA. For Lupin, all these point to likely headwinds to profitable growth in near – medium term.

Key Risks

1) Delay in the resolution of USFDA issues at its plants

2) Slower-than-expected ramp-up in gAlbuterol

3) Currency risk

Additional Data

Key management personnel

Mrs. Manju D Gupta	Non-Executive Chairman
Ms. Vinita Gupta	Chief Executive Officer
Mr. Nilesh Deshbandhu Gupta	Managing Director
Mr. Ramesh Swaminathan	CFO

Source: Company

Top 10 shareholders

Sr. No.	Holder Name	Holding (%)
1	Life Insurance Corp India	8.23
2	ICICI Prudential AMC	5.49
3	ICICI Prudential Housing Fund	5.05
4	HDFC Trustee Company Ltd.	4.08
5	Vanguard Group	2.04
6	Nippon Life India AMC	1.85
7	HDFC Life Insurance	1.59
8	BlackRock Inc.	1.59
9	Norges Bank	1.57
10	Govt Pension	1.24

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

Sharekhan

by BNP PARIBAS

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