

Sector: Pharmaceuticals
Result Update

	Change
Reco: Hold	↔
CMP: Rs. 759	
Price Target: Rs. 840	↑

↑ Upgrade ↔ No change ↓ Downgrade

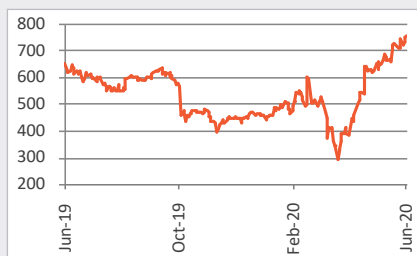
Company details

Market cap:	Rs. 44,482 cr
52-week high/low:	Rs. 791/281
NSE volume: (No of shares)	61.5 lakh
BSE code:	524804
NSE code:	AUROPHARMA
Sharekhan code:	AUROPHARMA
Free float: (No of shares)	28.1 cr

Shareholding (%)

Promoters	52.0
FII	22.8
DII	12.6
Others	12.66

Price chart



Price performance

(%)	1m	3m	6m	12m
Absolute	16.3	45.8	67.7	16.1
Relative to Sensex	9.2	57.3	84.5	31.3

Sharekhan Research, Bloomberg

Aurobindo Pharma Limited's (Aurobindo's) results for Q4FY2020 were better than estimates. Sales grew in double digits, by 16.4% to Rs. 6,158 crore because of sturdy 23% y-o-y growth in the formulations business. Double-digit growth across all regions drove the formulations segment's revenues. The API segment reported a drop of 17.6% y-o-y. Operating margins at 21.8% expanded by 180 bps y-o-y led by a sharp expansion in gross margins, attributable to favorable mix and benefits of low costs raw material inventory. Operating profit, at Rs. 1,342 crore grew by 26.6% y-o-y. Adjusting for one-offs, PAT stood at Rs 882 crore, rising 41% y-o-y and was ahead of the estimates of Rs. 751 crore. Aurobindo derives almost half of its revenues from the US and hence is exposed to the stringent USFDA regulations. Recently, the company has witnessed easing of the USFDA pressures with unit-4 being cleared by the USFDA, which had a substantial 47 product filings. However, this only partially eases the pressures, as five of its units are still under the USFDA scanner. The management is done with the remedial actions and is working towards resolution of the issues with the regulator. The recent retraction of an acquisition deal would eliminate concerns around rising debt levels and would strengthen the balance sheet. As a substantial chunk of the filings awaiting approvals, are from facilities that are under the USFDA scanner, the US business is likely to remain feeble. We believe the uncertainty related to regulatory hurdles would be an overhang until fully resolved.

Key positives

- Revenue grew strongly by 16.4% y-o-y, on a high base of the corresponding quarter.
- Formulations business recorded a 23% y-o-y growth backed by a double digit growth across geographies.
- Operating margins expand 180 bps y-o-y to 21.8% backed by an expansion in gross margins.

Key negatives

- API segment revenues continued to drop, falling by 17.6%.
- USFDA regulatory hurdles at fiveplants (unit I, IX, XI, VII and New Jersey) remain an overhang.

Our Call

Valuation - Maintain Hold with arevised PT of Rs.840: Aurobindo derives around half of its revenues from the highly regulated market of the US, while Europe accounts for almost a quarter of the revenues. Hence, the company is exposed to the stringent norms of the regulators. With the USFDA clearing the company's unit-4, regulatory concerns seem to be easing, though only partially. Aurobindo's five plants are still under the USFDA scrutiny with an OAI / WL status. Consequently, new approvals from these plants would be with held, leading to a likely slower growth. Aurobindo's Q4FY2020 results are better than estimates with a healthy all-round performance. At CMP, the stock trades at a valuation of 14.4x / 13.6x its FY2021 / FY2022E earnings. The withdrawal of an US acquisition has put to rest concerns regarding higher debt and points at improved balance sheet position. This coupled with the clearance of the unit-4 led to a sharp ~ 84% run up in the stock price since March 2020, thus leaving a limited upside. Further, new approvals are the key drivers for growth, as the base business in the US is fairly large. Hence, timely and proper resolution of the USFDA issues is critical. We believe the uncertainty related to regulatory hurdles would be an overhang on the stock (until they are resolved successfully). Thus, we maintain our Hold rating on the stock with a revised PT of Rs. 840.

Key Risks

Delay in resolution of USFDA issues and product approvals; change in regulatory landscape; and negative outcome of key facility inspection by USFDA can affect earnings prospects.

Valuation (Consolidated)

Particulars	FY18	FY19	FY20	FY21E	FY22E
Total Income	16499.8	19563.6	23098.0	24833.5	26681.1
OPM (%)	23.0	20.2	21.1	21.2	21.5
Adj. PAT	2440	2513	2913	3080	3273
EPS (Rs)	41.6	42.9	49.7	52.6	55.9
PER (x)	18.2	17.7	15.3	14.4	13.6
EV/EBIDTA (x)	13.0	12.9	9.7	8.7	7.4
P/BV (x)	3.8	3.2	2.6	2.3	2.0
ROCE (%)	21.9	16.8	17.7	18.4	18.1
RONW (%)	23.2	19.7	19.0	16.9	15.4

Source: Company; Sharekhan estimates

Results better than estimates: Aurobindo's Q4FY202 results are better than estimates. The revenues at Rs 6,158 crore y-o-y was up by a strong 16.4% y-o-y. A robust 23.5% growth in the formulations segments primarily drove up revenues. All geographies reported a double digit growth, with the key markets of US and Europe clocking a 20% and 26% y-o-y growth. Operating margins, at 21.8% expanded by 180 bps y-o-y. This compares with the estimate of 20.7%. The 420 bps y-o-y expansion in gross margins to 59.4% is attributable to favorable product mix and benefits of low cost raw material inventory, which drove up OPM. Operating profit, at Rs 1,342 crore was up 26.6% y-o-y and was ahead of estimates. During the quarter, the company reported an exceptional expense of Rs. 13.9 crore y-o-y. This includes a onetime gain / reversal of acquisition cost amounting to Rs. 12.25 crore y-o-y and a forex loss of Rs 26.19 crore y-o-y, towards borrowings. Also the share of loss from the JV's is up steeply at Rs. 19.31 crore y-o-y v/s Rs 0.52 crore y-o-y in corresponding quarter. Consequently, the adjusted PAT for the quarter stood at Rs 882 crore y-o-y, up by 41.2% y-o-y and ahead of the estimates of Rs 751 crore y-o-y. Reported PAT for the quarter stood at Rs 849 crore.

Regulatory risks yet to wane off completely: Of late, Aurobindo has witnessed partial easing of the regulatory pressures from the USFDA. The regulator has cleared the unit-4 of the company, which is a sterile manufacturing facility. The approval accorded is based on the possible shortages of injectables in the US. This has partially eased off regulatory pressures as unit-4 has around 47 ANDAs filed and of this, company plans to launch a sizeable chunk in FY2021. However five of the company's plants are still under the USFDA's scrutiny. Three units – units 1, 9 and 11, which were inspected by the USFDA in February 2019 continue to be under OAI status. Unit 11 has received a warning letter in July 2019. In January 2020, the USFDA indicated an OAI (Official Action indicated) status for unit-7 (inspected in October 2019). The facility manufactures oral solids and accounts of around 20% of US sales. With the OAI status, the approval would be held back. Moreover, of this, around eight fillings have APIs linked to unit-11, which has received a warning letter (WL). Also, the company's plant at New Jersey, has been classified as an OAI. Aurobindo has submitted the CAPA reports for unit 7 to the FDA on June 3, 2020 and is coordinating for further approvals. For units 1, 9 and 11 the company has already submitted its responses to the USFDA in November 2019 and is awaiting a revert. However, it has also requested for a desktop audit for these three facilities, albeit the USFDA is still working out the contours of the same. Substantial chunk of Aurobindo's filings are from units which are under regulatory scanners. Hence, successful resolution in a timely manner is a key monitorable. Until successfully resolved, these regulatory issues would continue to be an overhang. As the US constitutes around half of the company's consolidated revenues, a complete resolution of the USFDA issues is critical for future growth prospects.

Q4FY2020 Conference call highlights

- ♦ US revenues, at Rs.2,990 crore, were up 20.5% y-o-y and accounted for 50% of consolidated revenues. On a constant currency basis, growth was 17%.
- ♦ During the quarter the company got approval for 6 ANDAs, filed for 17 ANDAs, including 10 injectables and has launched 4 products. As of FY2020, the company cumulatively filed for 586 ANDA's with the USFDA and has received 425 approvals including 28 tentative approvals.
- ♦ In FY2021, Aurobindo plans to launch 50-60 new products and off this it already has approvals from the regulators for around 23 products.
- ♦ EU formulations business revenues grew sturdily by 26% y-o-y to Rs.1,652 crore. The segment constituted 26% of consolidated sales.
- ♦ Anti-retroviral (ARV) revenues, at Rs.381.8 crore, grew by 30.9% y-o-y and accounted for 6.2% of revenues. The revenues from the growth markets stood at Rs 376.6 y-o-y and constituted around 6.1% of consolidated revenues.
- ♦ The API segment revenues at Rs 755.6 crore declined sharply by 17.6% y-o-y on the back of a steep drop in non-beta lactam revenues, which were down by 35.2% y-o-y. Aurobindo filed 1 DMF with the USFDA during the quarter.
- ♦ R&D cost for Q4FY2020 stood at Rs. 238.9 crore, translating in to 3.9% of sales. For the full year FY2020, total R&D spends stood at Rs 958 y-o-y translating to 4.1% of the sales. Going ahead, the management has guided for R&D spends of 5-6% of sales.

Results

					Rs cr
Particulars	Q4FY20	Q4FY19	YoY %	Q3FY20	QoQ %
Total Income	6158.4	5292.2	16.4	5895.0	4.5%
Operating profit	1342.4	1060.3	26.6	1208.0	11.1%
Other income	32.6	32.3	1.0	22.0	48.2%
EBIDTA	1375.0	1092.6	25.8	1230.0	11.8%
Interest	31.8	50.1	-36.4	37.1	-14.2%
Depreciation	232.4	186.6	24.5	250.1	-7.1%
PBT	1110.8	855.9	29.8	942.8	17.8%
Adjusted PAT	882.2	624.8	41.2	709.9	24.3%
Margins			BPS		BPS
OPM (%)	21.8	20.0	176	20.5	131

Source: Company; Sharekhan Research

Q4FY2020 Revenue mix

					Rs cr
Particulars	Q4FY20	Q4FY19	YoY %	Q3FY20	QoQ %
USA	2990.3	2481.1	20.5	2969.4	0.7
Europe	1652.5	1311.8	26.0	1476.3	11.9
Emerging markets	376.6	289.1	30.3	345.9	8.9
ARV	381.8	291.5	31.0	313.4	21.8
Formulations	5401.2	4373.5	23.5	5105.0	5.8
Betalactams	539.2	583.0	-7.5	511.1	5.5
Non Betalactams	216.4	333.7	-35.2	278.7	-22.4
API	755.6	916.7	-17.6	789.8	-4.3
Gross Sales	6156.8	5290.2	16.4	5894.8	4.4
Dossier Income	1.7	1.9	-10.5	0.3	-
Net Sales	6158.5	5292.1	16.4	5895.1	4.5

Source: Company; Sharekhan Research

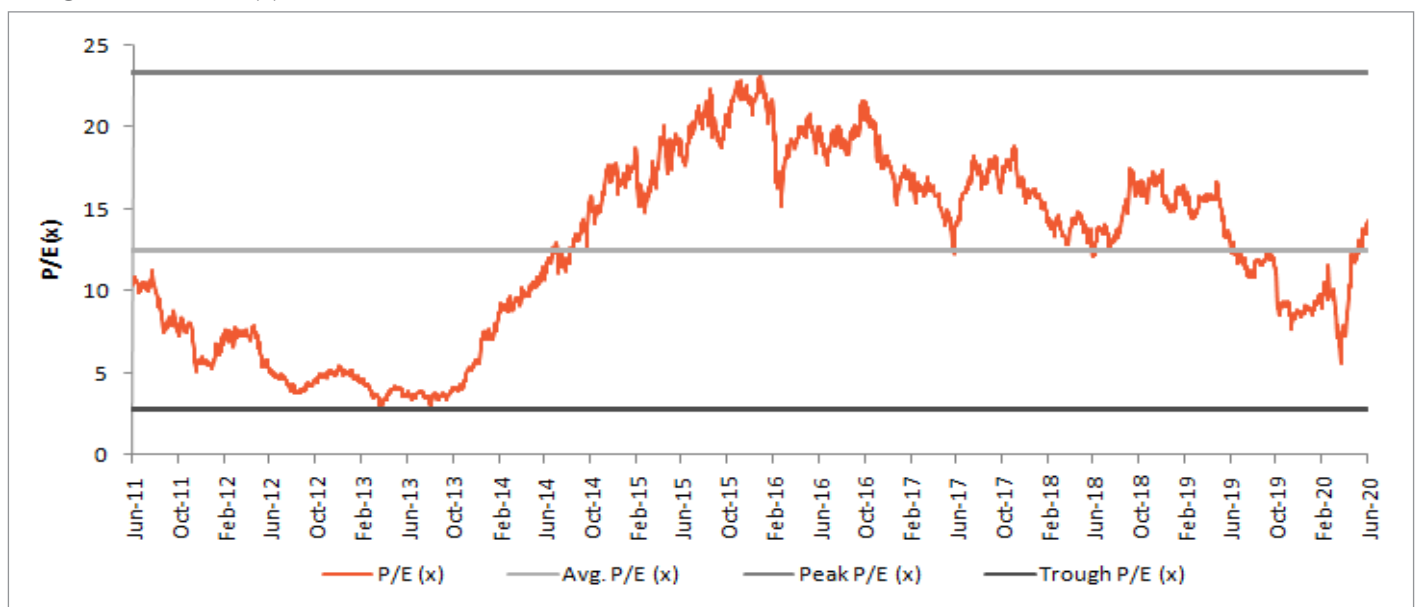
Outlook

Regulatory issues overweigh: Aurobindo is a leading Indian pharmaceutical company with presence in the formulations as well as in the API space. The company is a leading player in the generics space. Recently, the management withdrew a major acquisition planned in the US, which was expected to result in high debt. With the deal retracted, concerns around debt have subsided and consequently, the balance sheet is likely to improve. More than 90% of the company's sales are from exports and the US constitutes around half of the sales. Consequently, the company is exposed to the risk of USFDA regulatory hurdles. Recently, however, regulatory pressures seem to easing a bit with USFDA clearing the Unit-4, which had sizeable chunk of product filings approvals. Aurobindo plans to launch new products from this facility going ahead. However, the company is yet to get USFDA clearance for five of its plants and so new product approvals from these are awaited, consequently, slowing down the growth in the US business. A successful resolution of USFDA observations would be a key parameter to watch and will be a trigger for an earnings upgrade.

Valuation

Maintain Hold with arevised PT of Rs.840: Aurobindo derives around half of its revenues from the highly regulated market of the US, while Europe accounts for almost a quarter of the revenues. Hence, the company is exposed to the stringent norms of the regulators. With the USFDA clearing the company's unit-4, regulatory concerns seem to be easing, though only partially. Aurobindo's five plants are still under the USFDA scrutiny with an OAI / WL status. Consequently, new approvals from these plants would be with held, leading to a likely slower growth. Aurobindo's Q4FY2020 results are better than estimates with a healthy all-round performance. At CMP, the stock trades at a valuation of 14.4x / 13.6x its FY2021 / FY2022E earnings. The withdrawal of an US acquisition has put to rest concerns regarding higher debt and points at improved balance sheet position. This coupled with the clearance of the unit-4 led to a sharp ~ 84% run up in the stock price since March 2020, thus leaving a limited upside. Further, new approvals are the key drivers for growth, as the base business in the US is fairly large. Hence, timely and proper resolution of the USFDA issues is critical. We believe the uncertainty related to regulatory hurdles would be an overhang on the stock (until they are resolved successfully). Thus, we maintain our Hold rating on the stock with a revised PT of Rs. 840.

One-year forward P/E (x) band



Source: Sharekhan Research

Peer valuation

Particulars	CMP (Rs / Share)	O/S Shares (Cr)	MCAP (Rs Cr)	P/E (x)			EV/EBIDTA (x)			RoE (%)		
				FY20E	FY21E	FY22E	FY20E	FY21E	FY22E	FY20E	FY21E	FY22E
Aurobindo Pharma	759.0	58.6	44,482.0	15.3	14.4	13.6	9.7	8.7	7.4	19.0	16.9	15.4
Sun Pharma	495.0	239.9	118,764.0	29.5	23.3	19.2	17.3	14.0	11.9	8.9	10.2	11.2

Source: Sharekhan Research

About company

Hyderabad-based Aurobindo was incorporated in 1986 and manufactures generic formulations and active pharmaceutical ingredients (APIs). Aurobindo generates 90% of its sales from international markets. The company currently holds a strong position in the US, where it is the fifth largest generic pharmaceutical company as per the IMS National Prescription Audit, measured by total prescriptions dispensed for the 12 months ending June 2018. The company also holds a strong position in many European countries, including France and Italy, where it ranks among the largest generic companies. Aurobindo is a vertically integrated company, meeting around 70% of its API requirements in-house. Aurobindo has 26 manufacturing facilities for its API and formulations businesses, which have requisite approvals from various regulatory authorities, including the USFDA, U.K. MHRA, Japan PMDA, WHO, Health Canada, MCC South Africa and ANVISA Brazil. Recently, Aurobindo entered Poland and the Czech Republic with the acquisition of Apotex's commercial operations. The company also strengthened its US presence with the acquisition of dermatology and oral solid businesses from Sandoz.

Investment theme

Aurobindo has one of the best product approval rates and launch pipelines in the US. Despite pricing pressures, the company is one of the few companies able to mitigate this risk due to continuous product launches and approvals. The company is currently grappling through a USFDA scrutiny at its various plants. Continued regulatory concerns are likely to adversely impact performance going ahead, as more than 50% of the company's fillings are from plants that are under USFDA scrutiny.

Key Risks

Delay in product approvals; change in regulatory landscape; and negative outcome of key facility inspections by the USFDA can affect earnings prospects.

Additional Data

Key management personnel

K Nithyananda Reddy	Vice - Chairman, Whole-time Director, One of the promoters.
N Govindarajan	Managing Director
P.V. Ramaprasad Reddy	Non-executive Director, Promoter
Santhanam Subramanian	CFO

Source: Company Website

Top 10 shareholders

Sr. No.	Holder Name	Holding (%)
1	HDFC Asset Management Co Ltd	8.1
2	Axis Clinicals Ltd	3.0
3	Vanguard Group Inc/The	1.6
4	BlackRock Inc	1.5
5	Reliance Capital Trustee Co Ltd	1.3
6	Amansa Holdings Pvt Ltd	1.1
7	Dimensional Fund Advisors LP	1.1
8	ICICI Prudential Life Insurance Co	0.6
9	Aditya Birla Sun Life Asset Manage	0.5
10	Causeway Capital Management LLC	0.4

Source: Bloomberg;

Data as on 31st December 2019

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