Sharekhan
by BNP PARIBAS

Aurobindo Pharma

Regulatory overhang persists

Sector: Pharmaceuticals

Result Update

	Change
Reco: **Hold**	↔
CMP: **Rs. 433**	
Price Target: **Rs. 500**	↓

↑ Upgrade ↔ No change ↓ Downgrade

Company details

Market cap:	Rs. 25,395 cr
52-week high/low:	Rs. 838/428
NSE volume: (No of shares)	34.4 lakh
BSE code:	524804
NSE code:	AUROPHARMA
Sharekhan code:	AUROPHARMA
Free float: (No of shares)	28.2 cr

Shareholding (%)

Promoters	51.9
FII	22.5
DII	13.0
Others	12.63

Price chart

Price performance

(%)	1m	3m	6m	12m
Absolute	-0.3	-26.9	-41.5	-46.1
Relative to Sensex	-5.9	-32.0	-46.2	-53.6

Sharekhan Research, Bloomberg

Aurobindo Pharma Limited (Aurobindo) reported in-line results for Q2FY2020. Sales grew strongly by 18% to Rs. 5,600 crore because of sturdy growth in the U.S. and Europe formulations business. Operating profit grew by 14% y-o-y to Rs. 1,168 crore, while adjusted PAT was almost flat y-o-y to Rs. 679.5 crore, in line with our estimates. Aurobindo is witnessing higher USFDA scrutiny in the recent past, pointing at elevated regulatory risks. More than 50% of the company's fillings are from impacted plants; hence, resolution is a key parameter to watch. Management is confident of submitting the responses in a timely manner. However regulatory issues would continue to be an overhang until successfully resolved. Moreover, we believe margins and profitability are likely to remain restricted until the integration of assets acquired by the company is completed. We expect sales/PAT to report a CAGR of 19%/10% over FY2019- FY2021.

Key Positives

- Revenue grew strongly by 18%, while operating profit increased by 14% y-o-y.
- Debt-reduction guidance maintained at $150 million-200 million (already achieved in H1); ex-Sandoz, the company expects net debt to become zero in the next three years.

Key Negative

- Sandoz deal has taken longer-than-estimated time to close.
- USFDA regulatory hurdles remain an overhang.

Our call

Valuation - Maintain Hold with a revised PT of Rs. 500: Aurobindo's stock price has almost halved from its highs and the stock is trading at a beaten-down valuation of 8.3x its FY2021 earnings. 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. Moreover, remediation and site transfer-related costs and integration of acquisitions could stress the company's margins in the near term. We have cut our earnings estimates for FY2020/FY2021 to factor in the concerns. We expect the company to report sales and profit CAGRs of 19% and 10%, respectively, in the next two years. We feel the uncertainty related to regulatory hurdles at various units will weigh on the stock (until resolved successfully). Thus, we maintain our Hold rating on the stock with a revised price target (PT) of Rs. 500.

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

Valuation (Consolidated) Rs cr

Particulars	FY2018	FY2019	FY2020E	FY2021E
Total Income	16499.8	19563.6	25209.5	27776.8
OPM (%)	23.0	20.2	20.0	20.0
Adj. PAT	2440	2513	2657	3058
EPS (Rs)	41.6	42.9	45.4	52.2
PER (x)	10.4	10.1	9.5	8.3
EV/Ebidta (x)	7.9	8.1	6.2	5.5
P/BV (x)	2.2	1.8	1.5	1.3
ROCE (%)	21.9	16.8	17.0	16.5
RONW (%)	23.2	19.7	17.5	16.9

Source: Company; Sharekhan estimates

Results in line with estimates: Aurobindo's Q2FY2020 results were in line with estimates. Consolidated revenue grew by 18% y-o-y to Rs. 5,600 crore, driven by strong growth in the U.S. and Europe formulations business, though API business remained soft. Operating profit rose by 14% y-o-y to Rs. 1,168 crore. Operating margin at 20.8% dropped by 75 BPS y-o-y. Gross margin improved by 70 BPS y-o-y to 57.7%. Aurobindo reported an exceptional cost of Rs. 12.76 crore towards acquisition-related cost. Adjusted PAT at Rs. 679.5 crore is almost flat and is broadly in line with our estimate of Rs. 661 crore.

Regulatory risks continue: Recently, Aurobindo has been witnessing high scrutiny from the USFDA. The company has received a warning letter for its Unit-XI. As per management, the main reason for the warning letter is the issue pertaining to impurities in Sartan. Moreover, unit I and IX are classified as OAI. Management has indicated that it shall submit its responses to USFDA by November 15, 2019, and expects the inspection of all the three plants in January – March 2020 quarter. Further, Aurobindo's plants V and VIII (both API plants) were inspected by the USFDA between October 21-25, 2019. The USFDA has issued Form 483 with four observations for each facility. In addition, unit VII was inspected between September 19-27, 2019, and ended with seven observations, though none of them pertain to data-integrity issues. More than 50% of Aurobindo's filings are from Unit I, IV, IX, XI. Hence, successful resolution is the key monitorable. Though management seems confident of submitting its reply to the regulatory issues above, this would continue to be an overhang until successfully resolved.

Integration of recently acquired assets crucial; Rise in margin could be restricted: In the past six months, Aurobindo has done a series of acquisitions (funded by debt), namely R&D assets in Australia (for $12.5 million), units of Sandoz (for $900 million) and Apotex (for $82 million) with a total consideration value of ~$1 billion. The acquired portfolio of Sandoz is expected to generate over $0.9 billion in sales for the first 12 months after completion of the transaction for Aurobindo, before any potential Federal Trade Commission (FTC)-led divestments. The acquisitions are yet to be completed and a successful integration would be crucial for a short-to-mid-term perspective. We believe until completion of the acquisitions, rise in margins and profitability could be restricted by the increase in expenses, interest costs (as acquisitions will be funded by debt) and depreciation (due to assets bought). Moreover, remediation and site transfer costs are likely to put pressure on near-term margins.

Q2FY2020 Conference call highlights

- The formulations segment's revenue at Rs. 4,794 crore was ~86% of Q2FY2020 revenue and grew by 22% y-o-y.
- Revenue from the U.S. formulations and Europe formulations business grew sturdily by 27% and 21% y-o-y, respectively, for the quarter. Growth markets and ARV segment's revenue increased by 3.8% and 2.5% y-o-y, respectively. API revenue was almost flat at Rs. 817 crore.
- Aurobindo received final approval for three ANDAs and tentative approval for one ANDA from USFDA.
- Aurobindo filed for 20 ANDAs during Q2FY2020, which includes two injectables. The company received final approval for 3 ANDAs and tentative approval for one ANDA. In the API business, the company filed three DMFs during the quarter.
- As of September 30, 2019, on a cumulative basis, the company filed for 569 ANDAs and received approvals for 416 ANDAs, which includes 27 tentative approvals.
- R&D cost for the quarter stood at Rs. 223 crore, 4% of sales.

Results					Rs cr
Particulars	**Q2FY2020**	**Q2FY2019**	**YoY %**	**Q1FY2020**	**QoQ%**
Total Income	5600.5	4751.4	17.9	5444.6	2.9%
Operating expenditure	4433.0	3725.4	19.0	4298.2	3.1%
Operating profit	1167.5	1026.0	13.8	1146.4	1.8%
Other income	20.6	26.3	-21.5	11.0	87.5%
EBIDTA	1188.1	1052.3	12.9	1157.4	2.6%
Interest	40.9	35.4	15.7	49.9	-17.9%
Depreciation	243.3	163.7	48.6	240.9	1.0%
PBT	903.8	853.2	5.9	866.7	4.3%
Tax	224.4	175.4	27.9	227.8	-1.5%
Adjusted PAT (Ex forex)	679.5	677.8	0.2	638.9	6.3%
Except. Item	-39.7	-66.8	-40.5	0.2	-18159.1%
Reported PAT	639.7	611.0	4.7	639.1	0.1%
Adj. EPS (Rs)	11.6	11.6	0.2	10.9	6.3%
Reported EPS (Rs	10.9	10.4	4.7	10.9	0.1%
			BPS		**BPS**
OPM (%)	20.8	21.6	-75	21.1	-21

Source: Company; Sharekhan Research

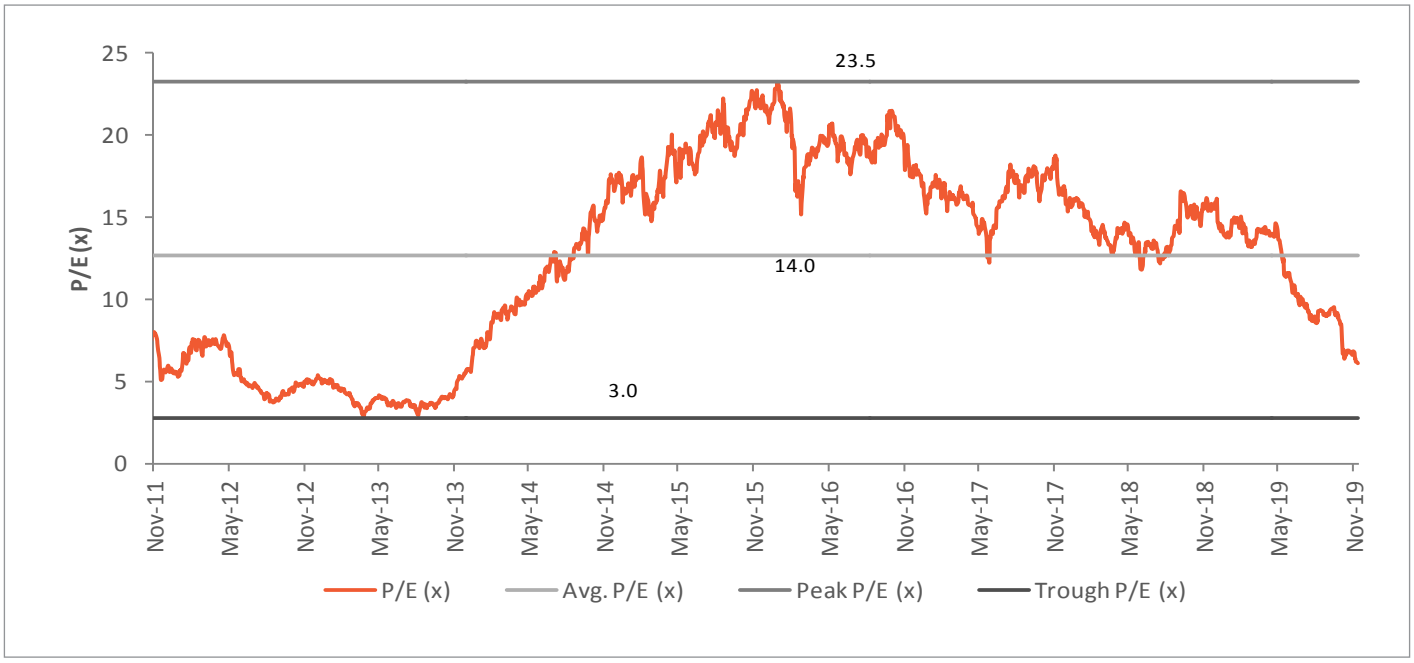
Outlook

Aurobindo's results came in line with our estimates. However, the company is grappling with elevated scrutiny issues from the USFDA. The company's various plants are under USFDA regulatory issues and more than 50% of the company's fillings are from these plants. Consequently, a successful resolution of USFDA observations would be a key parameter to watch and will be a trigger for earnings upgrade. Moreover, the integration of assets acquired in the recent past are likely to stress margins and profitability until fully completed.

Valuation

Maintain Hold with a revised PT of Rs. 500: Aurobindo's stock price has almost halved from its highs and the stock is trading at a beaten-down valuation of 8.3x its FY2021 earnings. Continued regulatory concerns are likely to adversely impact performance going ahead, as more than 50% of the company's fillings are from the plants that are under USFDA scrutiny. Moreover, remediation and site transfer-related costs and integration of acquisitions could stress the company's margins in the near term. We have cut our earnings estimates for FY2020/FY2021 to factor in the concerns. We expect the company to report sales and profit CAGRs of 19% and 10%, respectively, in the next two years. We feel the uncertainty related to regulatory hurdles at various units will weigh on the stock (until resolved successfully). Thus, we maintain our Hold rating on the stock with a revised PT of Rs. 500.

One-year forward P/E (x) band



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 U.S., 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 U.S. 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 U.S. 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. Moreover, remediation and site transfer-related costs and integration of acquisitions could stress the company's margins in the near term.

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	Rani Penaka Suneela	33.5
2	HDFC Asset Management Co Ltd	7.5
3	Reddy K Nithyananda	4.3
4	REDDY KAMBAM KIRTHI	3.5
5	PENAKA VENKATA RAMPRASAD R	3.1
6	Reddy P V Ramaprasad	3.1
7	Axis Clinicals Ltd	3.0
8	Sivakumaran M	2.5
9	Vanguard Group Inc/The	1.7
10	BlackRock Inc	1.5

Source: Bloomberg

Sharekhan

by BNP PARIBAS

Know more about our products and services

For Private Circulation only

Disclaimer: This document has been prepared by Sharekhan Ltd. (SHAREKHAN) and is intended for use only by the person or entity to which it is addressed to. This Document may contain confidential and/or privileged material and is not for any type of circulation and any review, retransmission, or any other use is strictly prohibited. This Document is subject to changes without prior notice. This document does not constitute an offer to sell or solicitation for the purchase or sale of any financial instrument or as an official confirmation of any transaction. Though disseminated to all customers who are due to receive the same, not all customers may receive this report at the same time. SHAREKHAN will not treat recipients as customers by virtue of their receiving this report.

The information contained herein is obtained from publicly available data or other sources believed to be reliable and SHAREKHAN has not independently verified the accuracy and completeness of the said data and hence it should not be relied upon as such. While we would endeavour to update the information herein on reasonable basis, SHAREKHAN, its subsidiaries and associated companies, their directors and employees ("SHAREKHAN and affiliates") are under no obligation to update or keep the information current. Also, there may be regulatory, compliance, or other reasons that may prevent SHAREKHAN and affiliates from doing so. This document is prepared for assistance only and is not intended to be and must not alone be taken as the basis for an investment decision. Recipients of this report should also be aware that past performance is not necessarily a guide to future performance and value of investments can go down as well. The user assumes the entire risk of any use made of this information. Each recipient of this document should make such investigations as it deems necessary to arrive at an independent evaluation of an investment in the securities of companies referred to in this document (including the merits and risks involved), and should consult its own advisors to determine the merits and risks of such an investment. The investment discussed or views expressed may not be suitable for all investors. We do not undertake to advise you as to any change of our views. Affiliates of Sharekhan may have issued other reports that are inconsistent with and reach different conclusions from the information presented in this report.

This report is not directed or intended for distribution to, or use by, any person or entity who is a citizen or resident of or located in any locality, state, country or other jurisdiction, where such distribution, publication, availability or use would be contrary to law, regulation or which would subject SHAREKHAN and affiliates to any registration or licensing requirement within such jurisdiction. The securities described herein may or may not be eligible for sale in all jurisdictions or to certain category of investors. Persons in whose possession this document may come are required to inform themselves of and to observe such restriction.

The analyst certifies that the analyst has not dealt or traded directly or indirectly in securities of the company and that all of the views expressed in this document accurately reflect his or her personal views about the subject company or companies and its or their securities and do not necessarily reflect those of SHAREKHAN. The analyst further certifies that neither he or its associates or his relatives has any direct or indirect financial interest nor have actual or beneficial ownership of 1% or more in the securities of the company at the end of the month immediately preceding the date of publication of the research report nor have any material conflict of interest nor has served as officer, director or employee or engaged in market making activity of the company. Further, the analyst has also not been a part of the team which has managed or co-managed the public offerings of the company and no part of the analyst's compensation was, is or will be, directly or indirectly related to specific recommendations or views expressed in this document. Sharekhan Limited or its associates or analysts have not received any compensation for investment banking, merchant banking, brokerage services or any compensation or other benefits from the subject company or from third party in the past twelve months in connection with the research report.

Either SHAREKHAN or its affiliates or its directors or employees / representatives / clients or their relatives may have position(s), make market, act as principal or engage in transactions of purchase or sell of securities, from time to time or may be materially interested in any of the securities or related securities referred to in this report and they may have used the information set forth herein before publication. SHAREKHAN may from time to time solicit from, or perform investment banking, or other services for, any company mentioned herein. Without limiting any of the foregoing, in no event shall SHAREKHAN, any of its affiliates or any third party involved in, or related to, computing or compiling the information have any liability for any damages of any kind.

Compliance Officer: Mr. Joby John Meledan; Tel: 022-61150000; email id: compliance@sharekhan.com;

For any queries or grievances kindly email igc@sharekhan.com or contact: myaccount@sharekhan.com

Registered Office: Sharekhan Limited, 10th Floor, Beta Building, Lodha iThink Techno Campus, Off. JVLR, Opp. Kanjurmarg Railway Station, Kanjurmarg (East), Mumbai – 400042, Maharashtra. Tel: 022 - 61150000. Sharekhan Ltd.: SEBI Regn. Nos.: BSE / NSE / MSEI (CASH / F&O / CD) / MCX - Commodity: INZ000171337; DP: NSDL/CDSL-IN-DP-365-2018; PMS: INP000005786; Mutual Fund: ARN 20669; Research Analyst: INH000006183;