

Sector: Pharmaceuticals
Stock Update

	Change
Reco: Hold	↓
CMP: Rs. 608	
Price Target: Rs. 710	↓

↑ Upgrade ↔ No change ↓ Downgrade

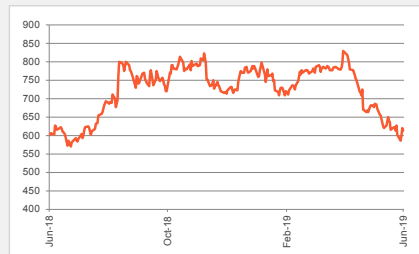
Company details

Market cap:	Rs. 35,623 cr
52-week high/low:	Rs. 838/566
NSE volume: (No of shares)	25.1 lakh
BSE code:	524804
NSE code:	AUROPHARMA
Sharekhan code:	AUROPHARMA
Free float: (No of shares)	28.2 cr

Shareholding (%)

Promoters	51.9
FII	22.0
DII	13.7
Others	12.40

Price chart



Price performance

(%)	1m	3m	6m	12m
Absolute	-10.2	-21.0	-13.8	-0.3
Relative to Sensex	-10.2	-24.2	-22.5	-12.4

Sharekhan Research, Bloomberg

A Warning Letter has been issued to Aurobindo Pharma Limited (Aurobindo) for its Unit-XI, an Active Pharmaceutical Ingredient (API) unit in Srikakulam, one of the three plants that received Official Action Indicated (OAI) status in May 2019. The letter mainly pertains to the ongoing issues regarding impurities in Sartan's. The company proposes to enter into dialogue with the US FDA over the next 15–20 days to decide a future course of action. From Unit XI, the company has ~28 filings that await approval, the delay of which may negatively impact performance ahead.

Regulatory hurdles increase

In Feb 2019, Unit- XI received three observations as follows: 1) lack of appropriate specifications for lab controls; 2) inadequate investigations that failed to evaluate potential root causes; and 3) inadequate master production batch records for API manufacturing. The plant was designated as OAI by the USFDA in March 2019. Aurobindo received OAI for two other API plants—unit I in Sangareddy (with six observations) and unit IX in the Medak district (with five observations). As with Unit XI, these both plants have been called out for 'inadequate investigations that failed to evaluate potential root causes'. Aurobindo has also received ten observations for unit III (oral formulations plant) and 11 observations for the sterile formulations unit. An increase in potential regulatory risks for Aurobindo may impact future approvals.

Our Call

Downgrade to Hold with downward revised PT of Rs 710

With a pattern emerging with the issues at all the API units, threat of warning letters for its other units cannot be ruled out. Although impact on existing businesses can be ruled out because of these developments, approval for future filings from these plants are likely to get delayed. Also, the remediation and site transfer related costs are likely to put the company's near term margins under pressure. The company is considering site transfer as a precautionary measure. Thus we have revised downwards our sales/earnings estimates for FY2020/ FY2021 by 4%/13% and 7%/14% respectively. We expect the company to report sales and profit CAGR of 29% and 22%, respectively, over the next two years. The uncertainty related to regulatory hurdles at various units will weigh on the stock (until resolved successfully). Thus we downgrade our recommendation to Hold with downward revised price target of Rs 710.

Key Risks

Delay in product approvals; Change in regulatory landscape; Negative outcome of key facility inspection by the USFDA can affect future earnings prospects.

Valuation (Consolidated)

Particulars	FY2018	FY2019	FY2020E	FY2021E
Net sales	16499.8	19563.6	29004.5	32456.3
OPM (%)	23.0	20.2	20.0	20.0
Adj. PAT	2440	2513	3212	3762
EPS (Rs)	41.6	42.9	54.8	64.2
PER (x)	14.6	14.2	11.1	9.5
EV/Ebitda (x)	10.7	10.6	7.2	6.3
P/BV (x)	3.0	2.6	2.1	1.7
Mcap/sales	2.2	1.9	1.3	1.1
ROCE (%)	21.9	16.8	19.9	19.3
RONW (%)	23.2	19.7	20.7	19.8

Source: Company Data; Sharekhan estimates

Recent Warning Letter increases regulatory risks

Aurobindo has received a Warning Letter for its Unit-XI, an Active Pharmaceutical Ingredient (API) unit in Srikakulam, one of the three plants that received Official Action Indicated (OAI) status in May 2019. As per the management, main reason for the warning letter is the ongoing issues pertaining to impurities in Sartan's. The company will have a dialogue with the US FDA over the next 15–20 working days to decide future course of action. From Unit XI, the company has ~28 filings that await approval (delay of which could potentially impact FY2020 and FY2021 performance).

In Feb 2019, Unit- XI had received three observations as follows: 1) lack of appropriate specifications for lab controls; 2) inadequate investigations that failed to evaluate potential root causes; and 3) inadequate master production batch records for API manufacturing. Post this, the plant was designated as OAI by the USFDA in March 2019. Along with unit XI, Aurobindo received OAI for two other API plants—unit I in Sangareddy (with six observations) and unit IX in the Medak district (with five observations). Both these plants have one observation common to unit XI ('inadequate investigations that failed to evaluate potential root causes'). Apart from these units, Aurobindo received ten observations for unit III (oral formulations plant) and 11 observations for the sterile formulations unit.

All these put together pose potential regulatory risks for Aurobindo and could impact future approvals until successfully resolved. Although existing businesses may not get impacted due to issued warning letter (for Unit- XI), approval for future filings done from these plants are likely to get delayed.

Regulatory Status of various units under FDA scrutiny

Units	Manufactures	USFDA Status	Inspection Time
API			
Unit I	API	OAI (6 observations)	Jan-19
Unit IX	Intermediates	OAI (5 observations)	Jan-19
Unit XI	API	OAI (3 observations); Warning Letter in Jun-19	Feb-19
Formulation			
Bachupally Unit – III	Oral Formulations	Form 483 with 10 obs	May-19
Telangana Unit – XVI	Sterile formulations	Form 483 with 11 obs	Feb-19

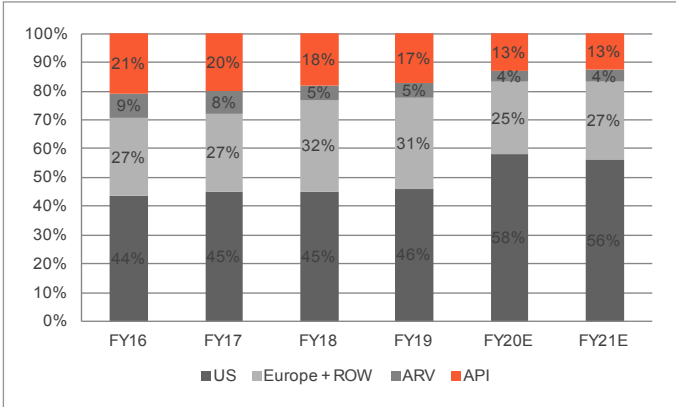
Integration of newly-acquired assets would be crucial; margin expansion restricted

In the past six months, Aurobindo has carried out a series of acquisitions (funded by debt), namely R&D assets in Australia (for US\$12.5mn), units of Sandoz (for US\$900mn) and Apotex (for US\$82mn) with a total consideration value of ~US\$1bn. 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 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 till the completion of acquisitions, margin expansion and profitability improvement would be restricted due to increase in expenses, interest cost (as acquisitions will be funded by debt) and depreciation (due to assets bought). Also, the remediation and site transfer related costs are likely to put pressure on company's near term margins.

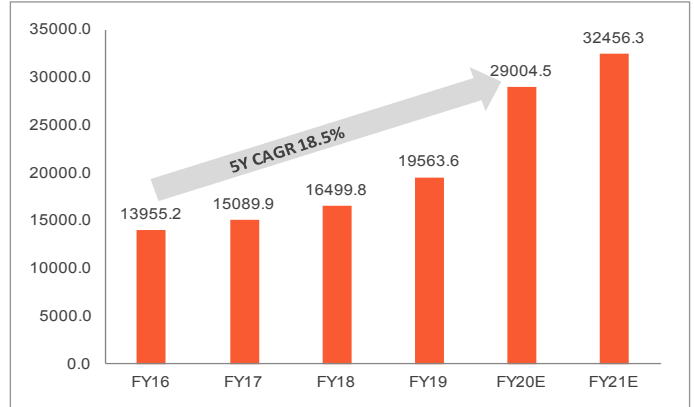
Financials in charts

Sales Mix



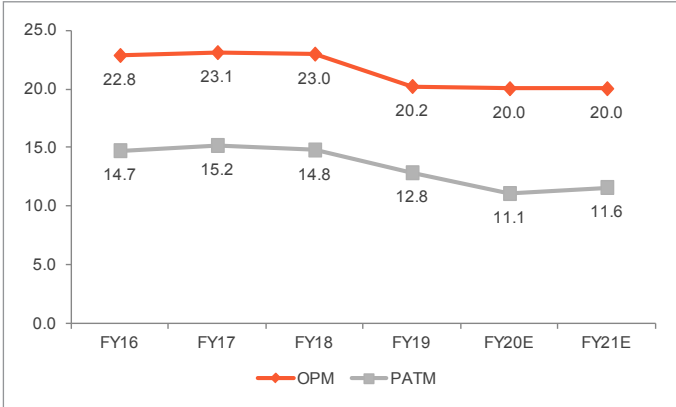
Source: Company Data; Sharekhan Research

Sales in Crore



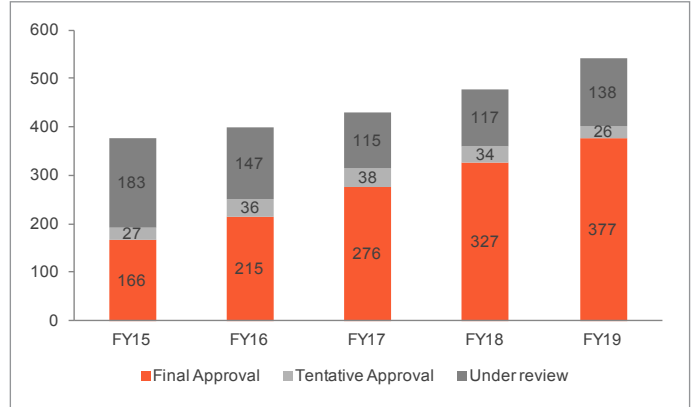
Source: Company Data; Sharekhan Research

OPM & Adj. PATM



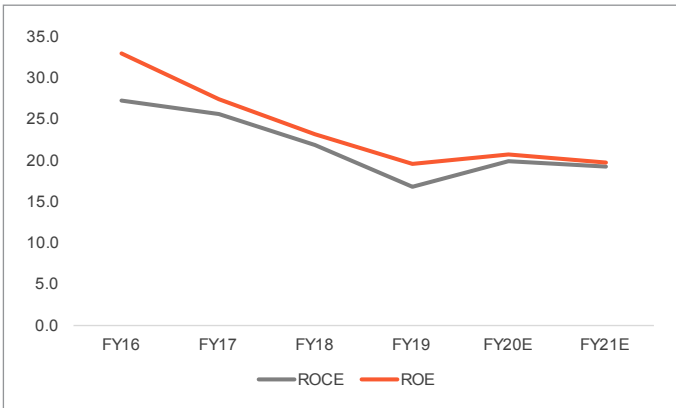
Source: Company Data; Sharekhan Research

US Filing Snapshot



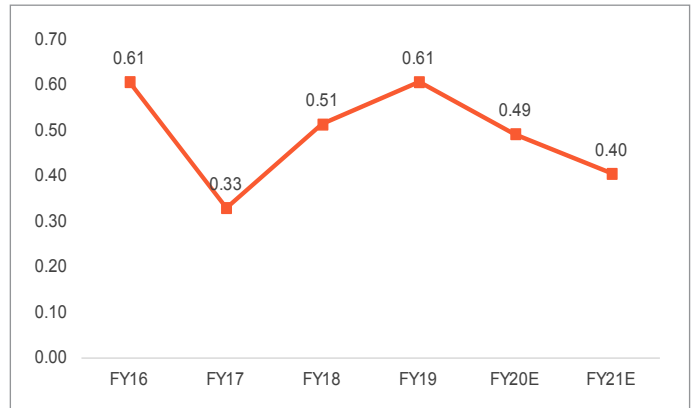
Source: Company Data; Sharekhan Research

Return Ratios



Source: Company Data; Sharekhan Research

Debt: Equity



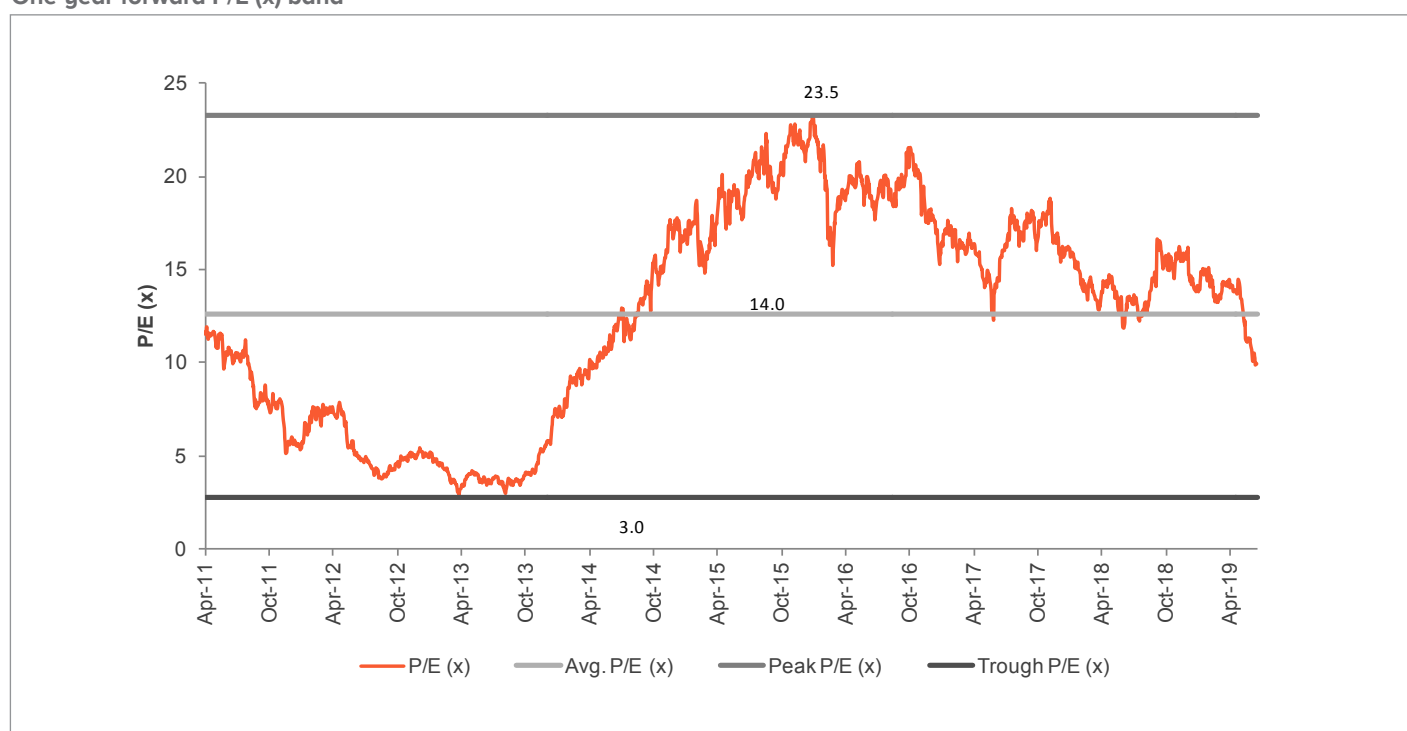
Source: Company Data; Sharekhan Research

Valuation: Downgrade to Hold with downward revised PT of Rs 710

With a pattern emerging with the issues at all the API units, threat of possibility of warning letters for its other units cannot be ruled out. Although impact on existing businesses can be ruled out because of these developments, may not get impacted due to issued warning letter (for Unit- XI), approval for future filings done from these plants are likely to get delayed. Also, the remediation and site transfer related costs are likely to put the pressure on company's near term margins under pressure. The company is considering site transfer as a precautionary measure. Thus we have revised downwards our sales/earnings estimates for FY2020/FY2021 by 4%/13% and 7%/14% respectively. We expect the company to report sales and profit CAGR of 29% and 22%, respectively, over 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 downgrade our recommendation to Hold with downward revised price target of Rs 710.

One-year forward P/E (x) band



Source: Sharekhan Research

About company

Aurobindo Pharma, a Hyderabad-based pharmaceutical company, was incorporated in 1986 and is manufacturer of generic formulations and Active Pharmaceutical Ingredients (API). Aurobindo generates 90% of its sales from international markets. It currently holds a strong position in the US market, where it is the 5th largest generic pharmaceutical company as per the IMS National Prescription Audit, measured by total prescriptions dispensed for the twelve months ending Jun 2018. It also holds a strong position in many European countries, including France and Italy where it ranks among the largest generic companies. It is a vertically integrated company with around 70% of its API requirement met in-house. Aurobindo has 26 manufacturing facilities for its API and formulations business, which has the requisite approval from various regulatory authorities including the US FDA, UK MHRA, Japan PMDA, WHO, Health Canada, MCC South Africa and ANVISA Brazil. Recently, Aurobindo entered Poland and the Czech Republic with the acquisition of commercial operations from Apotex. The company also strengthened its US presence with acquisition of dermatology and oral solid businesses from Sandoz.

Investment theme

Aurobindo has one of the best product approval rate and launch pipeline for US. Despite pricing pressure, it is one of the few companies who is able to mitigate this risk to due to continuous new launches and approvals. Also coupled with strong pipeline is low product concentration. Going ahead, progress of injectable launches is likely to sustain and be one of the key growth driver.

Key Risks

Delay in product approvals; Change in regulatory landscape; Negative outcome of key facility inspection by the USFDA can affect future earnings prospects.

Additional Data

Key management personnel

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

Source: Company

Top 10 shareholders

Sr. No.	Holder Name	Holding (%)
1	Rani Penaka Suneela	33.52
2	HDFC Asset Management Co Ltd	6.72
3	Reddy K Nithyananda	4.33
4	Reddy Kambam Kirthi	3.53
5	Reddy P V Ramaprasad	3.07
6	Penaka Venkata Ramaprasad	3.07
7	Axis Clinicals Ltd	2.97
8	Sivakumaran M	2.47
9	Vanguard Group Inc.	1.66
10	SBI Funds Management Pvt Ltd	1.62

Source: Bloomberg

Sharekhan Limited, its analyst or dependant(s) of the analyst might be holding or having a position in the companies mentioned in the article.

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;

Disclaimer: Client should read the Risk Disclosure Document issued by SEBI & relevant exchanges and the T&C on www.sharekhan.com; Investment in securities market are subject to market risks, read all the related documents carefully before investing.